DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

December 21, 1999

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
2121 Crystal Drive
Crystal Park 2, Suite 906
Arlington, Virginia 22202

Dear Commissioner Dickinson:

It was a pleasure meeting with you and your staff. We very much appreciated the opportunity to review the *Revised Written Description and Revised Utility Guidelines* and to further discuss with you the impact of PTO policies on the patenting of genes and gene fragments.

First, we were gratified to learn that the PTO has decided to make, in the words of Mr. Doll, a "180 degree turn" with respect to what constitutes an acceptable utility for patent purposes. One of our primary concerns about the published proposed guidelines has been the extent to which they will open the door to patenting genes and gene fragments of undisclosed (or only partially disclosed) biological function. We therefore applaud the PTO for acknowledging that general utilities for polynucleotides of undefined biological function are not sufficient.

In addition, we strongly support the three-pronged test for utility proposed by PTO, which requires a claimed invention to possess a specific, substantial, and credible utility. We believe that consistent application of this test will provide a sound framework for discriminating between those genes and gene fragments that confer specific benefit in a currently available form and those that are useful merely as an object of further research.

While we are pleased with the PTO's new stance on the utility of polynucleotides for which only generic utilities are asserted, we are very concerned with the PTO's apparent willingness to grant claims to polynucleotides for which a theoretical function of the encoded protein serves as the sole basis for the asserted utility. For example, as we noted in our recent meeting, a bold assertion that a claimed polynucleotide sequence is useful as a kinase, based solely on its homology to known kinases, is no less of a generic assertion of utility than the claim that the polynucleotide is useful for forensic studies or as a chromosome marker. The same argument would apply to many other gene families such as membrane-associated proteins, helicases, zinc fingers, traffic ATPases, etc. We therefore urge PTO to make clear in the Revised Utility Guidelines that a claim to a polynucleotide sequence supported solely by a theoretical characterization of the encoded protein is unlikely to possess specific utility.

Finally, we remain concerned that the PTO's apparent intention to allow "comprising claims" for partial gene sequences lacking any known biological function fails to satisfy the written description requirement and will result in the granting of patents of overly broad scope.

These concerns are addressed in further detail by Dr. Jack Spiegel in an enclosed letter. In closing, we found our recent discussions with the PTO useful toward understanding our respective missions and we look forward to further joint efforts to clarify the perceived ambiguities in the proposed *Revised Written Description and Revised Utility Guidelines.*

Sincerely,

/s/
Harold Varmus, M.D.
Director
National Institutes of Health

/s/
Francis Collins, M.D.
Director
National Human Genome Research Institute

Enclosure